UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-OP-45090 *The County of Cuyahoga v. Purdue Pharma L.P., et al.* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MANUFACTURER DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT FOR PLAINTIFFS' FAILURE TO OFFER PROOF OF CAUSATION

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INTRODUCTION

At the outset of this case, Plaintiffs made a tactical choice that they would try to satisfy their causation burden solely through aggregate proof. The consequences of that choice have now come due.

Plaintiffs ignored whether an individual Manufacturer's actions caused individual prescribing decisions, and whether those individual treatment decisions caused harm. They did not try to establish that any doctor actually relied on a Manufacturer's statement, which in turn caused the doctor to prescribe an opioid medication for a patient. Plaintiffs also made no effort to measure whether an individual Manufacturer's actions caused patients to abuse opioid medications or otherwise procure them without a lawful prescription, whether an individual Manufacturer's actions caused doctors to violate the law and intentionally write unnecessary prescriptions for profit, or whether an individual Manufacturer's actions caused drug cartels to import and sell illegal heroin and fentanyl in the Counties. Instead, Plaintiffs instructed their main causation expert to assume that ***all*** opioid promotion was unlawful from 1995 to the present—but no reasonable fact-finder could reach such a conclusion.

Plaintiffs' aggregate proof strategy is contrary to what the law requires them to prove, and Plaintiffs admit as much. In their recent Motion to Sever, Plaintiffs acknowledge they "will be required to prove their claims ***against each individual defendant based on each defendant's alleged wrongdoing***." *See* Dkt. 2099 at 2.[1] Just as in the Neonatal Abstinence Syndrome cases, where the Court recently explained that those plaintiffs had to "track the harm from Baby A to any one Defendant," Dkt. 2151 at 13:1-2, Plaintiffs here must "track the harm" from a particular Manufacturer to the specific injury (damages) for which they seek to recover. Nonetheless, nothing in their opposition brief changes the fact that Plaintiffs' aggregate proof—the only evidentiary theory on which they rely—does not "track the harm" back to any individual Manufacturer Defendant, let alone a Manufacturer Defendant's

[1] All emphasis is Manufacturer Defendants', unless otherwise stated.

alleged wrongful conduct.

In their opposition, Plaintiffs do not grapple with their failure to raise a genuine issue as to causation. Instead, Plaintiffs double down on the assumption their attorneys instructed their experts to make: that ***all*** marketing of prescription opioids by ***all*** Manufacturers was unlawful, no matter who said what to whom, whether it was consistent with the label, and whether it had any impact on prescribing. *See* Rosenthal Rpt. ¶ 75 (Dkt. 2000-23/1999-22); 5/4/2019 Rosenthal Dep. Tr. 149:24-150:7 (Dkt. 1970-11/1984-4).[2,3] Plaintiffs' case therefore requires proof that ***each and every instance*** of detailing of the Manufacturer Defendants' FDA-approved medicines since 1995 was "unlawful and fraudulent." Opp'n at 4, 51. Plaintiffs have not come close to showing that they can do this.

Plaintiffs make no effort to distinguish the effect of one Manufacturer's promotion from another's. They do not differentiate sales visits based on the subject of the visit, the length, the materials used, or when the visit happened. And, significantly, Plaintiffs make no effort to account for the conflict between the FDA's expert regulatory decision to approve prescription opioids as safe and effective to treat chronic non-cancer pain, and Plaintiffs' claims, which are rooted in the assumption that all marketing—even for that FDA-approved use—violates state law. They also ignore that the First Amendment protects lawful, non-misleading commercial speech. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). No Plaintiffs' expert can isolate this lawful, protected marketing.

It is not surprising that Plaintiffs stake out the absolutist position that all marketing is fraudulent: they seek to avoid their burden to prove that wrongful marketing caused prescribers in the Track One Counties to prescribe medically unnecessary/excess opioids. That position may be expedient, but it

[2] Initial citations to expert reports and deposition transcripts that are filed on the docket include the docket numbers for the sealed and public versions of those filings.

[3] On August 13, 2019, the Special Master struck Cutler's, Rosenthal's, and McGuire's "supplemental declarations" as untimely and prejudicial. Plaintiffs therefore may not rely on them in opposing Manufacturer Defendants' summary judgment motion. That Plaintiffs have asked the Special Master to formalize his ruling, presumably to set up an appeal, strongly suggests that they are concerned about the validity of their experts' analyses.

does not absolve Plaintiffs of their burden to prove that ***each*** Manufacturer Defendant actually engaged in ***fraudulent*** conduct, which caused prescriptions that would not otherwise have been written, which caused Plaintiffs' harms. It would be clear error to allow the case to proceed on Plaintiffs' all-or-nothing approach, for the record does not support it. Plaintiffs cannot recover for constitutionally-protected marketing consistent with the FDA-approved indications and labeling. Plaintiffs must isolate the effects of the alleged ***wrongful*** conduct. But because their experts have made no attempt to do so, the fact-finder will also not be able to do so. And Plaintiffs cannot cure that fundamental problem with a counterfactual assumption that lawful conduct was unlawful.

Plaintiffs fare no better in their attempt to salvage their claims predicated on Manufacturer Defendants' purported failure to control the distribution of prescription opioids. Because their SOM experts look only at shipments ***between distributors and pharmacies***, *see* 3/25/2019 McCann Rpt. at 56-74 (Dkt. 2000-14/1999-13), Plaintiffs offer no evidence that (1) any Manufacturer Defendant's alleged diversion-control failures caused excess opioid prescriptions in the Track One Counties, or (2) any Manufacturer Defendant's alleged diversion-control failures caused Plaintiffs' claimed injuries.

These two Plaintiffs had a choice. On one hand, they could try to prove causation the way plaintiffs in virtually all fraud cases do: by producing evidence of actual misrepresentations that caused actual harm. On the other hand, they could attempt to prove causation through expert testimony and aggregate proof. Plaintiffs chose the latter, and did so in a way that failed to measure the effect, if any, of the alleged wrongful conduct.[4] Instead, they provided only an expert whose analysis is fueled by an absurd assumption. Some other plaintiff may attempt to prove similar claims through actual evidence of fraud and causation. But because, as Manufacturer Defendants have shown, the Track One Plaintiffs'

[4] *See, e.g.*, Ex. 1, 12/31/2018 Pls.' Supp. Am. Resp. and Obj. to Manufacturer Defs.' First Set of Interrogatories at 2 ("Plaintiffs intend to rely, at trial and in expert opinions, on a theory of aggregate proof in asserting that Defendants' conduct violated the law and caused their damages and/or created a public nuisance, as alleged more fully in their Complaints and proved at trial.").

approach fails as a matter of law, they must be held to their election and summary judgment must be granted for Manufacturer Defendants.

ARGUMENT

I. Plaintiffs Get The Legal Standard For Causation Wrong.

Plaintiffs agree they must prove that Manufacturer Defendants' allegedly unlawful conduct was "both a cause-in-fact and a legal/proximate cause" of their alleged injury. Opp'n at 33. Plaintiffs, however, apply the wrong legal standard to both questions.

A. Plaintiffs Have Not Met Their Burden Of Showing That Any Manufacturer Defendant's Conduct Was A "Substantial Factor" In Causing Their Alleged Harms.

Plaintiffs are wrong that the evidence could support a finding of causation under the "substantial factor" test. *See* Opp'n at 33–34. Under that test, a defendant's conduct is the cause of harm only if the plaintiff can prove that the "conduct is a substantial factor in bringing about the harm." Restatement (Second) Torts § 431. But, with one exception, a defendant's conduct is "not a substantial factor in bringing about harm to another if the harm would have been sustained" in the absence of the defendant's misconduct.[5] *Id.* § 432(1). The only exception to this rule is where there is concurrent conduct by more than one actor, and the conduct of *each* was independently sufficient to cause "the harm." *Id.* § 432(2). But in that situation, there needs to be sufficient evidence that each actor's conduct would have by itself constituted a substantial factor in bringing about "the harm." *Id.* Plaintiffs have no such evidence for each Manufacturer Defendant, because Plaintiffs have not even attempted to show that "the conduct of each defendant, ***acting alone***, was sufficient to be a possible proximate cause of the [alleged] injury." *In re Bendectin Litig.*, 857 F.2d 290, 310 (6th Cir. 1988) (applying Ohio law); *see* Dan B. Dobbs et al., *The Law of Torts* § 189 (2d ed. 2011 & 2019 Update) (where multiple independent forces act to cause

[5] *See also* Restatement (Second) Torts § 431(a), cmt. a (causation requires showing "that the harm would not have occurred had the actor not been negligent," but that "is not enough"; the conduct also must be a "substantial factor in bringing about the harm").

a unitary harm, liability applies only to those causes that are "sufficient standing alone to cause the plaintiff's harm").

Plaintiffs suggest they "produced evidence sufficient to support a finding that ***each*** Defendant's wrongful conduct contributed to bring about their harm." Opp'n at 38 (emphasis in original). But even if they had done so (and they have not), evidence of some "contribution" is not enough, as explained above. Moreover, Plaintiffs never analyze the effect of each Defendant's allegedly wrongful conduct. Plaintiffs concede that Rosenthal's model "is intended to, and does, capture the ***average effect of all detailing***"—across Defendants and non-defendants, and without regard to whether any fraud occurred in a particular interaction. *See* Rosenthal *Daubert* Opp'n at 11 (Dkt. 2176). Thus, at most the model is capable of measuring the total effect of ***all*** the detailing by all manufacturers, whether or not Plaintiffs sued them—not the contribution of each individual Manufacturer Defendant, or each Manufacturer Defendant's alleged wrongful conduct. *See, e.g.*, *White v. Bell*, 656 F. App'x 745, 747-48 (6th Cir. 2016) (explaining that the "requirements of causation" are "individualized, and that "[t]he requirement of causation must be proven with respect to each defendant that the plaintiff seeks to hold liable"). Cutler likewise confessed that he had "not done anything with respect to any specific defendant." 4/26/2019 Cutler Dep. Tr. 68:12-13 (Dkt. 1961-9/1976-9). Thus, Plaintiffs have produced no evidence that would allow the fact-finder to determine whether any Manufacturer Defendant's alleged wrongful conduct was sufficient ***on its own*** to cause Plaintiffs' alleged harm. Plaintiffs' argument that they need not show that Defendants caused their "entire" harm is misplaced. *See* Opp'n at 37. This is not a question of damages apportionment, but of causation. Because Plaintiffs' experts cannot answer that question, summary judgment is warranted.

B. Plaintiffs Cannot Rely On An "Inference" To Prove Proximate Cause.

Plaintiffs repeatedly argue that causation can be inferred from the alleged conduct and ultimate harms, *see, e.g.*, Opp'n at 35, but that glosses over both Ohio law and the complexity of the causation

inquiries that necessarily underpin Plaintiffs' claims. *See Ramage v. Cent. Ohio Emergency Servs., Inc.*, 592 N.E.2d 828, 833 (Ohio 1992) ("Unless a matter is within the comprehension of a layperson, expert testimony is necessary.").[6] For example: How many, if any, opioid prescriptions in the Track One Counties were written by prescribers in reliance on a Manufacturer Defendant's alleged fraudulent marketing? What portion, if any, of the alleged opioid-related harms in the Track One Counties was caused by medically unnecessary/excess prescriptions that would not have been written but for a Manufacturer Defendant's false marketing? To what extent did a Manufacturer Defendant's diversion-control failures, if any, proximately cause excess shipments of the corresponding prescription opioid medications into the Track One Counties? Answering these, and other, complex questions is beyond the ken of the average juror; thus, Plaintiffs must produce expert testimony that can answer these questions. *See Viars v. Ironton*, No. 16CA8, 2016 WL 3670171, at *9 (Ohio Ct. App. July 6, 2016) ("Expert testimony is required to establish general causation and specific causation in cases involving flooding and soil erosion because the determination involves a scientific inquiry into matters beyond the knowledge or experience possessed by lay persons."); *Tormenia v. First Inv'rs Realty Co.*, 251 F.3d 128, 132 (3d Cir. 2000) (noting that, under New Jersey law, expert testimony is required "in cases where lay jurors confront causation issues that are too complex to be understood without the assistance of specialized expert testimony"). The bottom line is this: because of the shortcomings in Plaintiffs' experts' analyses, these causation-related questions have not been—and will never be—answered.[7]

[6] Unlike here, the causal chain in the mine-run cases Plaintiffs cite was simple and straightforward. *See Liriano v. Hobart Corp.*, 170 F.3d 264, 266 (2d Cir. 1999) (plaintiff injured hand in improperly protected meat grinder manufactured by defendant); *Brown v. Wal-Mart Stores, Inc.*, No. 98-5965, 1999 WL 1111514, at *6 (6th Cir. Nov. 24, 1999) (plaintiff injured by can that fell from improperly stacked shelf in defendant's store); *Empire Title Servs., Inc. v. Fifth Third Mortg. Co.*, No. 1:10cv2208, 2013 WL 1337629, at *10 (N.D. Ohio Mar. 29, 2013) ("This is not a case wherein the plaintiff sits parallel to the action, as in *Anza*; or attempts to recover in a linear fashion through and contingent upon the victims, as in *Holmes*.").

[7] *See, e.g.*, 5/4/2019 Rosenthal Dep. Tr. 150:8–153:5 (conceding that she was not asked "to examine th[e] question about whether [any] prescription[s]… [were] medically unnecessary," and explaining her view that "[t]he fact that the promotion was unlawful to me does not equate to the fact that a prescription was medically unnecessary"); 4/26/2019 Cutler Dep. Tr. 358:21-

II. Plaintiffs' Experts' Interdependent Analyses Do Not Prove Causation.

Defendants' *Daubert* briefing more fully addresses the deficiencies in Plaintiffs' experts' testimony and reasons for exclusion. Here, Manufacturer Defendants briefly address those experts because whether or not their testimony is permitted, it does not raise a genuine issue of fact on causation.

A. Plaintiffs' Experts Cannot Demonstrate That Any Manufacturer's Allegedly Fraudulent Marketing Proximately Caused Plaintiffs' Purported Injuries.

Meredith Rosenthal. According to Plaintiffs, "Rosenthal opines how the ***unlawful*** marketing here . . . increased the usage of all prescription opioids, not just that of a particular Manufacturer Defendant's product." Opp'n at 26. But Rosenthal concedes she is not offering any opinion about alleged unlawful marketing's causal effects because she does not distinguish fraudulent from non-fraudulent marketing.[8] She simply "operat[es] on the assumption that the defendants' conduct during the relevant period was unlawful." 5/4/2019 Rosenthal Dep. Tr. 219:20-220:7. Her analysis does nothing to distinguish between lawful and fraudulent detailing, let alone measure the effect of the latter. It thus does nothing to satisfy Plaintiffs' burden of showing that a particular Manufacturer Defendant's alleged ***fraudulent*** marketing caused prescribers to write medically unnecessary/excess prescriptions of that Manufacturer's opioid product.

David Cutler. Plaintiffs admit that "Dr. Rosenthal's analysis provides an important input for the analyses performed by Dr. Cutler and Dr. McGuire linking increased sales to increased harms and increased costs." Opp'n at 26. That presents an insurmountable hurdle for Plaintiffs: Cutler's reliance on Rosenthal's analysis means that Cutler likewise cannot and does not isolate the effects of lawful marketing from alleged fraudulent marketing. Plaintiffs are wrong when they say that Cutler computes

359:13 (Cutler "can't say whether any of the increase in mortality [i.e., the harms] that [he] attribute[s] to defendants resulted from individuals who actually got a prescription for one of the opioids that was manufactured or distributed by any defendant").

[8] *See* 5/4/2019 Rosenthal Dep. Tr. 219:20-220:7 (conceding that she was "operating on the assumption that the defendants' conduct during the relevant period was unlawful, and my model uses a single measure of detailing and therefore averages across allegedly lawful and unlawful details").

"the percentage of certain specific harms attributable to opioid shipments" and "the percentage of these harms attributable to Defendants' misconduct." Opp'n at 27. Like Rosenthal, Cutler does not measure the right relationship; Cutler's model measures only the relationship between ***all*** prescription opioid shipments and ***all*** opioid mortality from all opioids in 400 counties across the country. That is neither the misconduct nor the harm alleged. Cutler's analyses offer no evidence that Manufacturer Defendants' alleged unlawful conduct (individually or in aggregate) proximately caused Plaintiffs' alleged harms.[9]

Jonathan Gruber. Jonathan Gruber does nothing to help Plaintiffs' satisfy their burden to prove that Manufacturers' alleged fraudulent marketing caused prescribers to write medically unnecessary or excess opioid prescriptions and that those prescriptions proximately caused Plaintiffs' harms. His analysis focused on shipments, without regard to whether those shipments were causally linked to marketing, let alone allegedly fraudulent marketing. He did not even focus on shipments into Cuyahoga and Summit Counties. And although Plaintiffs admitted in their Motion to Sever that "different evidence is required for each defendant," Dkt. 2099 at 2, Gruber conceded that his analysis "[does] not differentiate between different pharmaceutical manufacturers" and is not even confined to the Manufacturer Defendants sued by Plaintiffs, *see* 4/25/2019 Gruber Dep. Tr. 58:3-20 (Dkt. 1962-15/1977-20).

Thomas McGuire. The only "damages" calculations that Thomas McGuire offers expressly derive from Rosenthal's estimates of the share of prescription opioid shipments purportedly due to marketing by Manufacturers. *See* McGuire Damages Rpt. ¶ 15 (Dkt. 2000-17/1999-16). As explained above, however, Rosenthal assumes that all Manufacturer Defendant marketing is unlawful—meaning

[9] Plaintiffs also reference the testimony of Drs. Perri, Keyes, Lembke, and Schumacher, but do not purport to suggest that they can carry Plaintiffs' causation burden. Indeed, none of these experts conducted any independent causation analysis—much less attempted to isolate the impact of Defendants' specific allegedly fraudulent marketing on providers in Ohio. These experts provide no evidence in support of causation.

that McGuire cannot isolate damages caused by alleged misconduct.

B. Plaintiffs' SOM Experts Fail To Provide Evidence That Manufacturer Defendants' Supposed Diversion-Control Failures Proximately Caused Plaintiffs' Harms.

Seth Whitelaw. The only Manufacturer Defendant about which Whitelaw purports to opine is Mallinckrodt, *see* Opp'n at 29, but he does not even offer an opinion as to whether any Mallinckrodt product was diverted. *See* 5/17/2019 Whitelaw Dep. Tr. 836:4-837:14 (Dkt. 1972-7/1985-19). That is not enough to prove causation with respect to Mallinckrodt, and it certainly cannot sufficient to prove causation with respect to any of the other Manufacturer Defendants. *See* Dkt. 2099 at 2 (Plaintiffs conceding that "different evidence is required for each defendant" and that they are "required to prove their claims against each individual defendant based on each defendant's alleged wrongdoing").

Craig McCann. Craig McCann did not evaluate any orders actually shipped by Manufacturer Defendants, let alone attempt to link such shipments to any diversion-control failure by a Manufacturer Defendant. Instead, he purports to calculate the aggregate number of transactions ***between pharmacies and distributors***, and then attempts to identify products included in those transactions. And even if McCann could "determine which Manufacturer's drugs were included in the orders flagged as suspicious," Opp'n at 30 n.7, that would say nothing about whether any diversion-control failures of that individual Manufacturer caused any harm to the Track One Counties.

James Rafalski. Plaintiffs concede that James Rafalski does not identify a single "suspicious order" that any Manufacturer Defendant shipped due to alleged distribution-control failures. *See* Opp'n at 31 (explaining Rafalski "assesses the number of oxycodone and hydrocodone orders shipped to the Plaintiff Counties ***by five Distributor Defendants***"). This is unsurprising, because Rafalski admitted that he does not offer any opinion that any particular order placed with a Manufacturer and eventually shipped into Summit or Cuyahoga County was, in fact, "suspicious." 5/14/2019 Rafalski Dep. Tr. 635:2-13; 823:8-824:8 (Dkt. 1969-19/1983-16) ("I do not identify any single suspicious order – any

order specifically that was suspicious.").

Lacey Keller. Plaintiffs do not—and cannot—dispute that Lacey Keller looked only at shipments ***between distributors and pharmacies***. They do not—and cannot—dispute that Keller did not identify a single "suspicious order" shipped by a Manufacturer as a result of alleged distribution-control failures. Nor do they dispute that Keller could not even opine whether the orders that were flagged by one or more of her sixteen made-up compliance metrics were even "suspicious." 6/13/2019 Keller Dep. Tr. 51:6-52:15 (Dkt. 1963-13/1979-6). Because she did not analyze orders shipped by any Manufacturer Defendant to a distributor, Keller did not analyze any order that the Manufacturers actually had the power or any purported reason to halt. Plaintiffs therefore cannot rely on Keller to prove that any Manufacturer's alleged diversion-control failures caused excess shipments of that Manufacturer's prescription opioids into the Track One Counties.

III. Plaintiffs' Attempt To Use Aggregate Proof Fails Here.

Manufacturer Defendants do not contend that aggregate proof can never be used to prove causation; the point is that Plaintiffs' approach to aggregation in this case proves nothing. At bottom, Plaintiffs' aggregate proof models, lumping together the lawful and alleged unlawful conduct of multiple defendants and non-defendants alike, do not even begin to meet Plaintiffs' burden of showing that alleged wrongful conduct by each Manufacturer Defendant caused the claimed harms.

UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 135 (2d Cir. 2010), is instructive. That was a class certification case, but the same fundamental lesson applies here. As in this case, the *UFCW* plaintiff relied on a fraudulent marketing theory. The court held that "general [aggregate] proof of but-for causation is impossible" because "at least some doctors were not misled by [Defendant's] alleged misrepresentations, and thus would not have written 'excess' prescriptions as identified by the plaintiffs." *Id.* at 135. Rosenthal's analysis is even more deficient than the aggregate evidence of causation plaintiffs attempted to rely upon in *UFCW*. Her regression model purports to measure the

aggregate effect of ***all*** detailing—fraudulent or not—on ***all*** prescription opioid sales nationwide. She never considers, and there would be no way for a fact-finder to determine from her analysis, whether any particular instance of detailing was fraudulent or what, if any, effect it had on prescribing. *See id.* Rosenthal simply assumes without factual basis that all detailing is fraudulent without extracting the "additional variables" that "interfere [ ] with plaintiffs' theory of causation." *Id.* Her analysis does nothing to provide the causal chain that Plaintiffs would need to create a genuine issue for trial.

Plaintiffs identify only one case, *In re Neurontin Marketing and Sales Practices*, 712 F.3d 21 (1st Cir. 2013), that allowed the use of an aggregate proof model with respect to false marketing claims, *see* Opp'n at 46-47, but that case is inapplicable here. That case involved a regression analysis purporting to measure the impact of off-label marketing by one defendant (Pfizer) on one medication (Neurontin)—not the dozens of each that are involved here—and the regression analysis distinguished between the wrongful off-label marketing and the marketing of the product for its FDA-approved use. 712 F.3d at 29-30. In other words, unlike here, the regression analysis in *Neurontin* was designed to measure the impact of the allegedly wrongful conduct, *i.e.*, the off-label marketing.

Rosenthal's analysis in *Neurontin* underscores why her work here is so problematic. In *Neurontin*, Rosenthal did not assume that ***all*** marketing was fraudulent—only that ***off-label*** marketing was—and she purported to measure the effect of the allegedly wrongful marketing. 712 F.3d at 33. Here, however, she purports to measure the impact of all detailing without regard to whether it was "wrongful" or not. There is no legal or factual basis in the record for her assumption that every instance of opioid detailing starting in 1995 was misleading—she made that assumption only because the Plaintiffs' lawyers told her to do so. Rosenthal herself concedes that she cannot identify which, if any, opioid prescriptions were medically improper and would not have been written but for the alleged wrongful conduct at issue in this case. *See* 5/4/2019 Rosenthal Dep. Tr. 150:8-153:5. Said differently,

in this case, unlike *Neurontin*, Rosenthal does not measure the effects of the alleged wrongful conduct and her analysis thus cannot provide proof of a causal link between the alleged wrongful conduct and harm.

Moreover, Plaintiffs do not even make a halfhearted effort to distinguish the more recent opinion in *Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, 873 F.3d 574 (7th Cir. 2017). Contrary to Plaintiffs' assertions, the Seventh Circuit did not affirm dismissal simply because the *Sidney Hillman* "plaintiffs failed even to identify any study addressing the prescription drug sales practices at issue." Opp'n at 47-48. In fact, the Seventh Circuit agreed "that the plaintiffs could not hope to show proximate causation" because no regression model could account for beneficial off-label prescriptions for which recovery would be improper. 873 F.3d at 575, 577. Likewise, the court explained that for an aggregate regression model to prove causation, it would have needed to account for other potential causes by "[d]isentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices." *Id.* at 577. Rosenthal fails to do so here.

In re High Fructose Corn Syrup Antitrust Litigation, 295 F.3d 651 (7th Cir. 2002), is of no help to Plaintiffs. *See* Opp'n at 49. There, plaintiffs' expert conducted a regression analysis that purported to isolate the impact of defendants' alleged unlawful price fixing. 295 F.3d at 660. Here, however, Rosenthal's model fails (and summary judgment is warranted) precisely because it cannot distinguish or account for lawful marketing by Manufacturer Defendants. And it is no answer that her analysis can address the question what would have happened if these manufacturers had not marketed their products at all, because there is no legal basis for arguing that marketing of FDA-regulated prescription opioid medications is per se unlawful. *See* 5/4/2019 Rosenthal Dep. Tr. 79:23-80:24 (Rosenthal admitting that she is "interested in understanding how marketing ***as a whole*** drove sales in this market"). Plaintiffs have failed to meet their burden of coming forward with evidence that could support a verdict in their

favor on the issue of causation. Summary judgment is required because no reasonable fact-finder could think that the model on which Plaintiffs rely proves a causal link between Manufacturer Defendants' alleged unlawful conduct and Plaintiffs' claimed injuries. Rosenthal herself admits that it does not.

Plaintiffs cannot meaningfully distance themselves from *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015). There, as here, Rosenthal's work failed to support an inference that fluctuations in prescription levels could be causally ascribed to fraudulent marketing. *Id.* at 91. She "simply 'assumed' that a downturn in [the drug's] sales was attributable to the disclosure of the previously hidden safety risks." *Id.* at 92. Rosenthal's analysis suffers from the same flaw here: she assumed that a causal relationship existed without actually measuring the effect of the alleged fraudulent conduct. Like her model in *Sergeants*, Rosenthal's model cannot demonstrate proximate cause.[10]

IV. The Court Has Not Already Ruled That Plaintiffs' Experts Have Demonstrated Proximate Causation.

Cornered by the case law, Plaintiffs argue that Manufacturer Defendants have somehow attempted a "backdoor challenge to this Court's prior proximate causation ruling," but there is no merit to this assertion for several reasons. *See* Opp'n at 48-49. As an initial matter, the Court's prior statements on this subject were at the pleading stage and related solely to the sufficiency of Plaintiffs' ***allegations***. "The purpose of a summary judgment motion, unlike that of a motion to dismiss, is to determine whether there is ***evidence*** to support a party's factual claims." *L & M Enterprises, Inc. v. BEI Sensors and Systems Co.*, 231 F.3d 1284, 1287 (10th Cir. 2000).

Moreover, even if the Court's motion-to-dismiss ruling laid out a potential path for Plaintiffs to

[10] Plaintiffs cannot take refuge in *Conwood Company, L.P. v. U.S. Tobacco Company*, 290 F.3d 768 (6th Cir. 2002). The experts in *Conwood* actually tried to create a model that could differentiate between defendants' lawful and unlawful conduct by "studying markets where the company had a foothold and those in which it did not." *Id.* at 780. Plaintiffs' experts' analyses here did no such thing. Because they merely assumed that all Manufacturer conduct was fraudulent and have no means of isolating legal conduct for which Manufacturer Defendants could never be held liable, Plaintiffs' experts cannot show causation.

prove that each Manufacturer Defendant's alleged misconduct proximately caused the claimed harms,[11] *see* Mfr. Defs.' Summ. J. Mot. re Causation ("Mot.") at 1, the "evidence" Plaintiffs developed in discovery did not follow that path. Plaintiffs' experts have not presented any method by which they can isolate the alleged "***deceptive*** claims" made by Manufacturer Defendants "in promoting their opioids" from those that were not deceptive and, accordingly, were not unlawful. Dkt. 1203 at 9-10. Because Plaintiffs have not done what the Court said they would need to do in order to prove causation, their claims must now be dismissed.

V. Plaintiffs Cannot Satisfy Their Causation Burden For Their Public Nuisance Claim.

Instead of responding to Manufacturer Defendants' argument that "Plaintiffs must prove that ***each Manufacturer*** proximately caused the" alleged absolute common law public nuisance, *see* Mot. at 22, Plaintiffs ignore it, *see* Opp'n at 57-58. But try as they might to sidestep the argument, they cannot avoid their obligation to prove causation as to each ***individual*** Manufacturer Defendant. The case law is clear, *see* Mot. at 22 (citing cases), and Plaintiffs fail to dispute it.[12] Just as they have failed to prove causation for their other claims, the evidence does not support a finding of causation for public nuisance.

The Court need not take Manufacturers' word for this point—Rosenthal and Cutler admitted they never attempted to measure the effects of any Manufacturer's alleged misconduct. Rosenthal conceded that her "assignment was to estimate the impact of the alleged misconduct and to quantify that ***in aggregate***." *See* 5/5/19 Rosenthal Dep. Tr. 752:21-23 (Dkt. 1970-12/1984-5). Cutler acknowledged that he had "not done anything with respect to any specific defendant." 4/26/19 Cutler Dep. Tr. 68:12-13. Because their experts did not examine whether any unlawful—as opposed to entirely legal—

[11] Manufacturer Defendants dispute that the potential chain of causation proposed by the Court in its motion-to-dismiss ruling would be legally sufficient.

[12] *See, e.g.*, *Rugiero v. Nationstar Mortg., LLC*, 580 F. App'x 376, 378 (6th Cir. 2014) (holding failure to respond to factual and legal arguments raised in summary judgment motion was sufficient basis for granting summary judgment).

conduct of any individual Manufacturer proximately caused the alleged nuisance, Plaintiffs cannot satisfy their burden to prove causation as to each individual Defendant. *Accord City of Mingo Junction v. Sheline*, 196 N.E. 897, 900 (Ohio 1935) ("Certainly what the law sanctions cannot be said to be a public nuisance.").

Just as Plaintiffs cannot prove that alleged ***fraudulent*** conduct of any Manufacturer Defendant proximately caused their claimed injuries, they cannot prove that any individual Manufacturer Defendant's alleged misconduct proximately caused the purported nuisance. Summary judgment thus should be granted for Manufacturer Defendants on Plaintiffs' common law public nuisance claim.

VI. Because Plaintiffs Cannot Prove Any Conduct In Furtherance Of The Alleged Conspiracies Caused Their Injuries, Their Conspiracy Claims Cannot Survive Summary Judgment.

Plaintiffs ignore the fundamental question regarding their conspiracy claims: "whether the predicate acts committed by co-conspirators ***in furtherance of the conspiracy—and only those acts***—proximately caused each of Plaintiffs' injuries." Mot. at 24. *See Beck v. Prupis*, 529 U.S. 494, 505-06 (2000). The issue here is not about what the "statistical analysis of aggregate data does," as Plaintiffs would have the Court believe. Opp'n at 56. It is whether Plaintiffs can prove that their alleged damages "proximately result from acts committed ***pursuant to a formed conspiracy***." *Lawyers Title Co., LLC v. Kingdom Title Sols., Inc.*, 592 F. App'x 345, 355 (6th Cir. 2014) (citation omitted). They cannot.

With respect to the RICO marketing conspiracy claims, Plaintiffs do not dispute that they must prove the racketeering activities of the RICO Marketing Defendants—***committed in furtherance of that conspiracy***—proximately caused their injuries. But the models relied on by Plaintiffs do not, and cannot, isolate the alleged racketeering activities purportedly committed in furtherance of the alleged Opioid Marketing Enterprise. Throughout the Complaint, Plaintiffs allege that Manufacturer Defendants promoted opioids through "front groups" and KOLs, and that such promotion forms the basis of the alleged marketing conspiracy. To prove these wide-ranging allegations, however, Plaintiffs

must show a causal link between this alleged conduct and the alleged conspiracy. *See Gosden v. Louis*, 687 N.E.2d 481, 497 (Ohio Ct. App. 1996) (holding that the alleged injury "cannot be the result of just any tort committed by a conspirator, or just any act committed in furtherance of the conspiracy," but "must have been caused by a tort [or torts] committed in furtherance of the conspiracy"). But that is impossible, because Plaintiffs did not even ask Rosenthal to review "front group" and KOL activity. By Plaintiffs' own admission, she evaluated only "detailing."[13]

The most Plaintiffs can do is point to a few paragraphs of Rosenthal's report and avow that they reflect an analysis of "aggregate harm based on the exclusion of each individual Manufacturer Defendant." Opp'n at 57 (citing Rosenthal Rpt. at 52-53). But Rosenthal's "sensitivity analysis" simply removes a Manufacturer Defendant in its entirety from the measure of "aggregate harm" that Rosenthal attributes to ***detailing***. *See* Rosenthal Rpt. ¶ 76. It does not measure the impact of KOLs nor demonstrate that the alleged predicate acts of the RICO Marketing Defendants caused prescribers to write medically unnecessary/excess prescriptions.

The RICO supply chain conspiracy claims fare no better. Plaintiffs do not dispute that they must prove that the racketeering activities of the RICO Supply Chain Defendants—***committed in furtherance of that conspiracy***—proximately caused their injuries. Instead, they assert that "Cutler estimated the harms that would not have occurred in the absence of supply chain misconduct, including that of Manufacturers and Distributor Defendants alike." Opp'n at 57. That is not true. Appendix III.J, which Plaintiffs cite as evidence of Cutler's estimations, is titled "Framework for Estimating Harms Due to ***Distributor*** Misconduct." Cutler Rpt. App'x III.J (Dkt. 2000-4/1999-4). Cutler even admitted that Appendix III.J of his report is "merely showing how to take an estimate of ***distributors'***—in this

[13] *See* Mem. in Support of Defs.' Mot. to Exclude Dr. Rosenthal at 1 (Dkt. 1913-1) (citing Rosenthal Rpt. ¶ 56 (Dkt. 1913-4) and 5/4/2019 Rosenthal Dep. Tr. 44:11–19 (Dkt. 1913-5)).

case an estimate that was provided to me of ***distributors'*** misconduct and calculate the harms that result from that. And nothing in Appendix J is specific to any single defendant." 4/27/2019 Cutler Dep. Tr. 602:23-603:6 (Dkt. 1961-10/1976-10).

Plaintiffs do not even try to defend their civil conspiracy claim. There is no dispute that this claim likewise requires proof that the allegedly tortious conduct committed in furtherance of an all-encompassing conspiracy—and only that conduct—caused Plaintiffs' harms. Because they do not and cannot offer that evidence, the Court should grant summary judgment for Defendants on this claim.

VII. Manufacturer Defendants Cannot Be Held Liable For Harms Stemming From Illegal Drugs Like Heroin And Street Fentanyl.

Plaintiffs' assertion that Defendants should be responsible for ***all*** harms caused by illicit heroin and street fentanyl is entirely without precedent. *See* Opp'n at 79-80. No reasonable factfinder could determine on this record that the manufacturers of prescription opioid medications proximately caused the activities of criminal gangs flooding American communities with deadly street drugs. But Plaintiffs are compelled to take that position because their experts cannot give the fact-finder any way to carve those harms out of their models, and making such calculations is not within the average juror's ken.[14]

Plaintiffs do not—and cannot—cite a single case from any court holding that the manufacturer of a lawful product may be liable for harms flowing from the use of illegal products with which the manufacturer had nothing to do. *See id.* Indeed, such a holding would be clear error. For example, no court would hold a licensed liquor manufacturer responsible for injuries arising from drinking illegally produced moonshine—even if the injured person usually drank the manufacturer's lawful product. There is no factual or legal basis for the Court to chart a new path here, particularly given the defects permeating Plaintiffs' experts' analyses as discussed above. And defects such as the inability to tie

[14] *See* 4/26/2019 Cutler Dep. Tr. 140:4-8 ("The direct model uses any opioid death as the dependent variable. It does not make a distinction between deaths due to use of licit opioids and deaths due to illicit opioids.").

causation specifically to fraudulent marketing or the inability to prove causation as to individual Manufacturer Defendants are even more acute with respect to these highly remote injuries arising from the use of illicit heroin and street fentanyl. At the very minimum, the Court should hold that Manufacturer Defendants cannot be found liable for harms caused by illicit drugs like heroin or fentanyl and dismiss Plaintiffs' claims to the extent they assert such a theory of liability.

CONCLUSION

To find proximate cause a triable issue based on Plaintiffs' evidence and theoretical regression analyses would stretch the concept to a point that would leave it with no meaning as an independent element of Plaintiffs' causes of action. Indeed, under Plaintiffs' theory, car manufacturers could be said to have "caused" public costs associated with vehicle accidents and traffic enforcement, and manufacturers of sugary cereals could be deemed the proximate cause of public healthcare costs associated with childhood obesity. Attractive as this may be to litigation financiers, it is completely untethered from controlling law and common sense.

As bookends to their opposition, Plaintiffs load up on quotes from documents and depositions in an attempt to demonstrate the existence of an issue of material fact. None of these cherry-picked statements would suffice to support a finding that any Defendant's alleged ***misconduct caused*** the harms Plaintiffs claim. Plaintiffs' experts do not fill the massive causation holes in Plaintiffs' case—nor do Plaintiffs offer any other evidence that could do so.

Plaintiffs could have attempted to prove that specific Manufacturer Defendants made fraudulent misrepresentations that actually caused doctors to write inappropriate prescriptions they would not otherwise have written, and that those inappropriate prescriptions then led to cases of addiction that ultimately increased costs to the Counties. But Plaintiffs opted otherwise, and chose to rely on expert testimony and aggregate proof to try to prove causation. In sum, Manufacturer Defendants have demonstrated that the approach taken by these two Plaintiffs simply cannot survive summary judgment.

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Respectfully submitted,

/s/ Mark S. Cheffo

Mark S. Cheffo
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Mark.Cheffo@dechert.com

Counsel for Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company

Co-Liaison Counsel for the Manufacturer Defendants[15]

/s/ Carole S. Rendon

Carole S. Rendon
BAKER & HOSTETLER LLP
Key Tower 127 Public Square, Suite 2000
Cleveland, OH 44114-1214
Telephone: (216) 621- 0200
Fax: (216) 696-0740
crendon@bakerlaw.com

Counsel for Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.; Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc.

Co-Liaison Counsel for the Manufacturer Defendants

[15] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction, they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of August 2019, the foregoing was served upon all counsel of record via email.

/s/ Donna M. Welch
Donna M. Welch, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Tel: (312) 862-2000